MAY 23 2002

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of the SMDA 1990 and 21 CFR Part 807.92.

The assigned 510(k) number is: K014192

1. Date of Summary: Dec. 13, 2001

2. Submitted by: Princeton BioMeditech Corporation
   4242 U.S. Route 1, Monmouth Jct., NJ 08852
   PHONE 732-274-1000
   FAX 732-274-1010

   Contact Person: Jemo Kang, Ph.D.

3. Device Name: Trade Names: Life Sign® Home Drug Test(MET)
   Common or Usual Name: Immunoassay for detection of methamphetamine in urine
   Classification Name: Drugs of Abuse Analysis Systems, Toxicology (91LAG for HPLC)

4. Identification of legally marketed device to which claims equivalence: k990786; Status DS™ DOA 10 (MET/OPI/COC/THC/PCP/BZO/BAR/MTD/TCA/AMP)

5. Device Description: Life Sign® Home Drug Test (MET) is simple one step immunochromatographic test for the rapid, qualitative detection of methamphetamine.

6. Intended Use:Life Sign® Home Drug Test (MET) is designed for the qualitative detection of methamphetamine at the cutoff of 1000 ng/mL in urine to assist in screening of drugs of abuse samples at home or work place. For *In vitro* Diagnostic Use

7. Substantial Equivalence: Life Sign® Home Drug Test (MET) is substantially equivalent to the k990786; Status DS™ DOA 10. Both products use the same assay principle and immunochromatographic assay to detect methamphetamine qualitatively. The detection cutoff level is the same. The tests demonstrate 100 % correlation when 94 specimens (50 negative and 44 positive) were compared. The difference is that Life Sign® Home Drug Test (MET) detects methamphetamine only, while Status DS™ DOA 10 detects nine other drugs of abuse in addition to methamphetamine.

8. Consumer Study: In a consumer study, LifeSign® Home Drug Test (MET) showed over 96% overall accuracy.

Conclusion: The device is substantially equivalent to a legally marketed device k990786, Status DS™ DOA 10 (MET/OPI/COC/THC/PCP/BZO/ BAR/MTD/TCA/AMP).

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   4242 U.S. Route 1, Monmouth Jct., NJ 08852
   PHONE 732-274-1000
   FAX 732-274-1010

   Contact Person: Jemo Kang, Ph.D.

3. Device Name: Trade Names: Stick Device: Status Stik™ MET, AccuSign® Stik MET, AccuStik™ MET
   Card Device: AccuSign® MET, Status DS™ MET
   Strip Test: AccuStrip™ MET
   Common or Usual Name: Immunoassay for detection of methamphetamine in urine
   Classification Name: Drugs of Abuse Analysis Systems, Toxicology (91LAG for HPLC)

4. Identification of legally marketed device to which claims equivalence: k990786; Status DS™ DOA 10 (MET/OPI/COC/THC/PCP/BZO/BAR/MTD/TCA/AMP)

5. Device Description: Status Stik™ MET is simple one step immunochromatographic test for the rapid, qualitative detection of methamphetamine.

6. Intended Use: Status Stik™ MET is designed for the qualitative detection of methamphetamine at the cutoff of 1000 ng/mL in urine to assist in screening of drugs of abuse samples. For *In vitro* Diagnostic, Prescription Use.

7. Substantial Equivalence: Status Stik™ MET is substantially equivalent to the k990786; Status DS™ DOA 10. Both products use the same assay principle and immunochromatographic assay to detect methamphetamine qualitatively. The detection cutoff level is the same. The tests demonstrate 100 % correlation when 94 specimens (50 negative and 44 positive) were compared. The difference is that Status Stik™ MET detects methamphetamine only, while Status DS™ DOA 10 detects nine other drugs of abuse in addition to methamphetamine.

Conclusion: The device is substantially equivalent to a legally marketed device k990786, Status DS™ DOA 10 (MET/OPI/COC/THC/PCP/BZO/ BAR/MTD/TCA/AMP).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAY 23 2002

Jemo Kang, Ph.D.
Director
Princeton BioMeditech Corporation
4242 U.S. Route 1
Monmouth Junction, NJ 08852-1905

Re: k014192
Trade/Device Name: LifeSign®Home Drug Test (MET)
Status Stik™ MET, AccuSign®Stik MET, AccuStik™ MET,
AccuSign® MET, Status DS™ MET, Strip: AccuStrip™ MET
Regulation Number: 21 CFR 862.3610
Regulation Name: Methamphetamine test system
Regulatory Class: Class II
Product Code: MVO; DJC
Dated: April 9, 2002
Received: April 10, 2002

Dear Dr. Kang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory-Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): _____

Device Name: LifeSign®Home Drug Test (MET)

Indications For Use:

Immunoassay for the qualitative detection of methamphetamine at the cut-off of 1000 ng/mL in urine to assist in screening of drugs of abuse samples at home and work place. For *In vitro* Diagnostic Use

Jean Cooper

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K014192

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH Office of Device Evaluation (ODE)

Professional Use:___
Prescription Use:___ OR Over The Counter Use: _X__
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

510(k) Number (if known): K014192

Device Name: Status Stik™ MET, AccuSign®Stik MET, AccuStik™ MET, AccuSign® MET, Status DS™ MET, Strip: AccuStrip™ MET

Indications For Use:

Immunoassay for the qualitative detection of methamphetamine at the cut-off of 1000 ng/mL in urine to assist in screening of drugs of abuse samples. For *In vitro* Diagnostic Use

Trade Names for each format

Stick: Status Stik™ MET, AccuSign®Stik MET, AccuStik™ MET
Card: AccuSign® MET, Status DS™ MET
Strip: AccuStrip™ MET

Jean Cooper

(Division Sign-Off)
Division of Clinical Laboratory D
510(k) Number K014192

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH Office of Device Evaluation (ODE)

Professional Use:___
Prescription Use: X OR Over The Counter Use: ___
(Per 21 CFR 801.109)

(Optional Format 1-2-96)